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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,570	05/23/2000	Francois Arminjon	MBHIB00-210	9141

7590 04/07/2003

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EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,570

Examiner

Stacy S Brown

Applicant(s)

ARMINJON ET AL.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2003.
- 2a) ☒ This action is **FINAL**.
- 2b) ☐ This action is non-final.

- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 21-27 and 29-38 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121:

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Office Action Summary

DETAILED ACTION

1. Applicant's amendment filed February 25, 2003 is acknowledged and entered. Claims 21-27 and 29-38 are pending and examined.

Response to Arguments

2. Claims 21-27 and 29-38 remain rejected under 35 U.S.C. 103(a) as obvious over Petre *et al.* in view of Arminjon *et al.*, both of record. Applicant's arguments have been carefully considered.

Applicant mainly argues that:

- The prior art does not suggest adsorption of tetanus and diphtheria toxoids onto aluminum salt prior to mixing with other components.
 - In response, Petre teaches that the components of the combined vaccine are adsorbed to AH or AP. The following excerpt is taken from Petre, "After allowing time for complete and stable adsorption of the respective components, the different components are combined under appropriate conditions", page 9, lines 1-3 of Petre. Therefore, Petre clearly teaches adsorption prior to mixing with other components.
- The prior art does not teach the preparation of a conjugate in phosphate buffer solution prior to mixing with other components.
 - In response, upon further review of the Arminjon reference, Arminjon discusses the immunogenic instability of HiB/PRP coupled to tetanus anatoxin. *Arminjon says that the PRP-T should be suspended in a solution*

containing anions (phosphate or citrate) prior to contacting them with aluminum complexes (page 6, lines 33-40). Therefore, the prior art teaches that PRP-T should be prepared in a buffer solution before mixing.

- There is no motivation to combine the teachings of Petre with those of Arminjon.
 - In response, it would have been obvious to modify the vaccine of Petre with the teachings of Arminjon because Arminjon teaches that the method used by Petre is not efficient (Arminjon, page 2, lines 20-26). Petre's method of retaining the immogenicity of the HiB antigen is to mix it with the other components immediately before administering (Petre, page 4, lines 17-20). However, Arminjon discloses the buffer solution to help stabilize PRP-T. Therefore, it would have been obvious to use Arminjon's buffer in Petre's multivalent vaccine.
- The limitations of the claims are not addressed in the rejection.
 - In response, Applicant is invited to review the prior Office actions of record where the limitations of the claims are addressed.
 - The limitation of claim 23 pertains to the addition of inactivated polio virus mixed with other components without being adsorbed onto an aluminum salt. Petre discloses instances where only one of the components of the multivalent vaccine is adsorbed to an aluminum salt (claim 27) and the other components are not treated. Given the teachings of Arminjon and Petre, one of ordinary skill would have recognized that any component of the multivalent vaccine could be adsorbed, depending

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on the stability required/desired for each component. This is demonstrated by the fact that Petre teaches that IPV can be adsorbed or not adsorbed onto aluminum salt (claims 6 and 27).

Conclusion

3. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

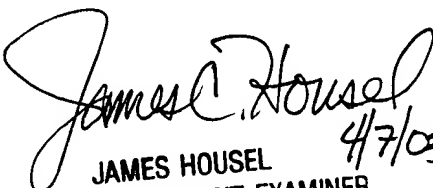
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
March 28, 2003



4/7/03
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600